

(12) UK Patent Application (19) GB (11) 2 348 138 (13) A

(43) Date of A Publication 27.09.2000

(21) Application No 0003118.7

(22) Date of Filing 14.02.2000

(30) Priority Data
(31) 990220 (32) 18.02.1999 (33) FR

(71) Applicant(s)
Tokendo (S.A.R.L.)
(Incorporated in France)
Bâtiment Alpha, Voie Ariane, Athelia I,
13600 La Ciotat, France

(72) Inventor(s)
Jean Rovegno
Jean-Francois Dumon

(74) Agent and/or Address for Service
Fry Heath & Spence
The Old College, 53 High Street, HORLEY, Surrey,
RH6 7BN, United Kingdom

(51) INT CL⁷
A61F 2/06

(52) UK CL (Edition R)
A6R RAT

(56) Documents Cited
WO 99/25280 A WO 89/07916 A US 5609627 A

(58) Field of Search
UK CL (Edition R) A5R RAT
INT CL⁷ A61F 2/06
ONLINE: EPODOC, WPI, JAPIO

(54) Abstract Title
System for setting a tracheal or bronchial endoprosthesis

(57) The system comprises a tubular bronchoscope having a proximal base (10) and a distal cannula (20), a prosthesis introducing device having a tubular holder (30) for prosthesis (60) insertable into an opening (12) in the base of the bronchoscope and a prosthesis driver (40) insertable into a proximal opening (33) in the base (34) of the prosthesis holder. The prosthesis driver (40) has an axial channel to enable an endoscope (50) to be introduced via an opening (43) in its base (44).

In operation (Figs 6-8 not shown), semi-rigid tubular prosthesis (60) is bent longitudinally and introduced into the distal end (31) of the prosthesis holder (30) which is then inserted into the bronchoscope. The prosthesis driver (40) is then inserted into the prosthesis holder until its distal end (41) abuts the proximal end of the prosthesis. An endoscope (50) is then introduced into the axial channel of the driver until the distal end (51) of the endoscope contacts the prosthesis. The prosthesis (60) is ejected by the operator's hand closing handles (35 and 45) attached to the holder and driver respectively.

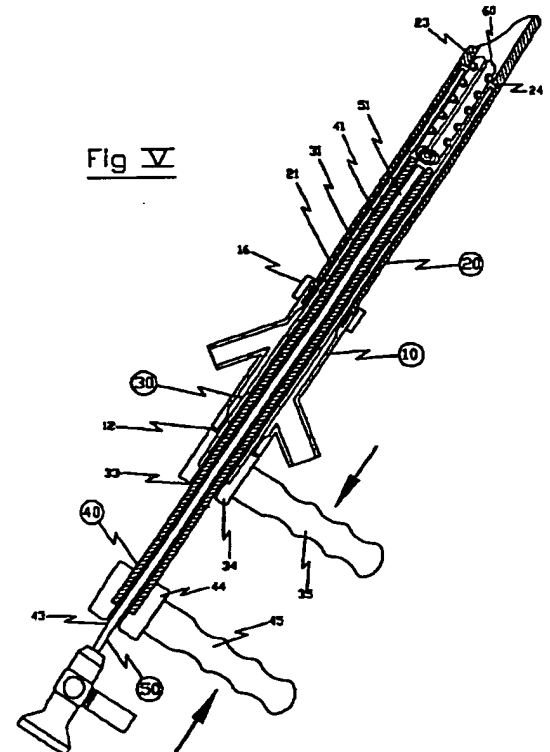


Fig I

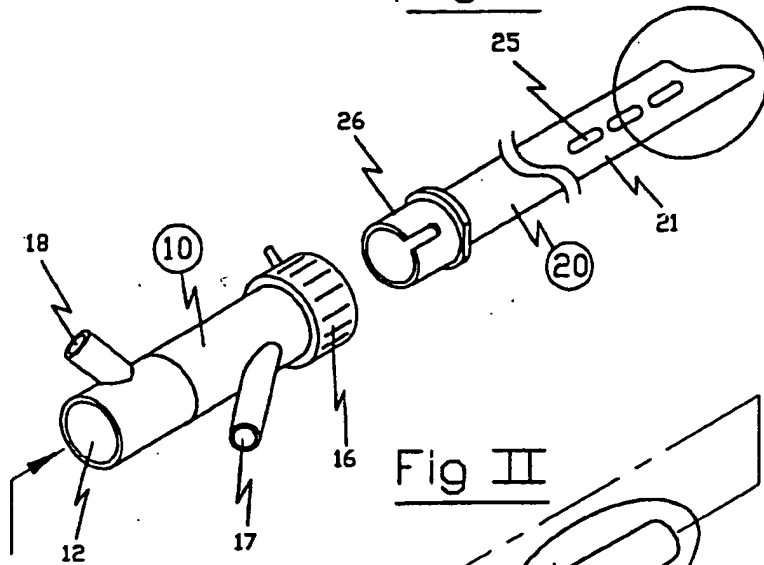


Fig I A

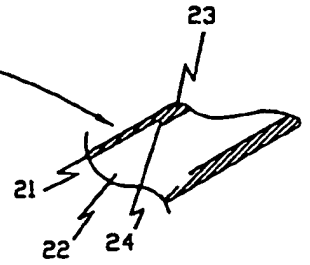


Fig II

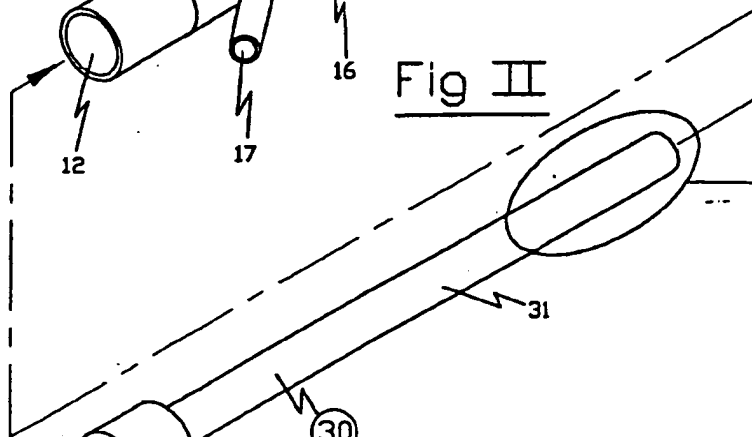


Fig II A

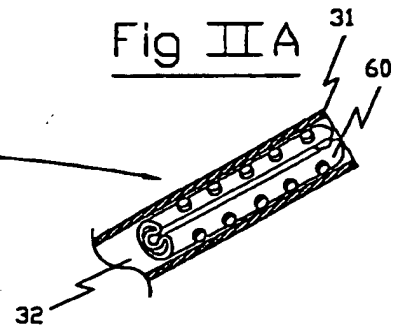


Fig III

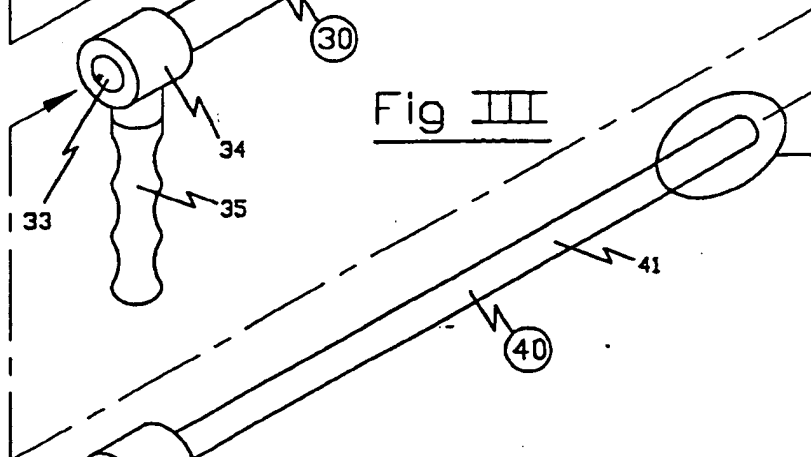


Fig III A

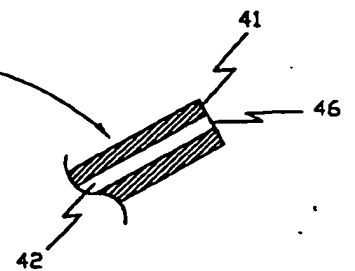


Fig IV

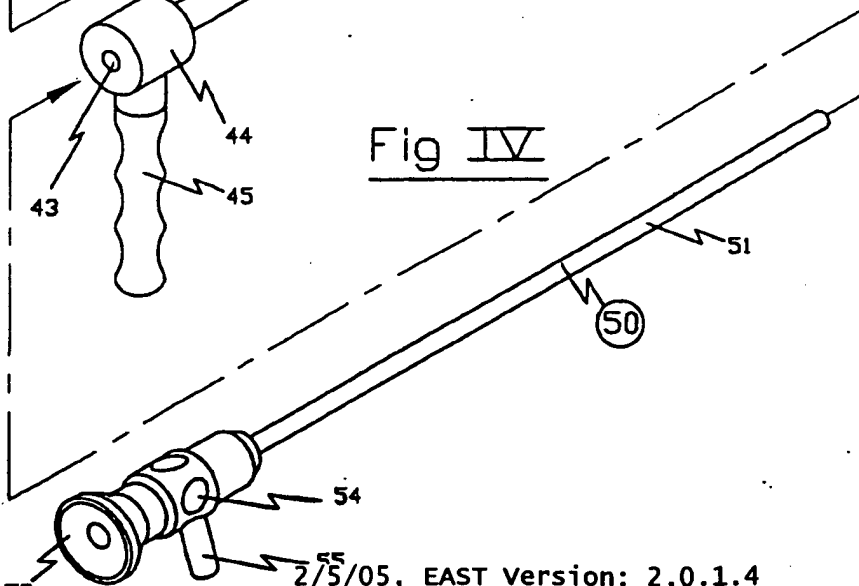


Fig V

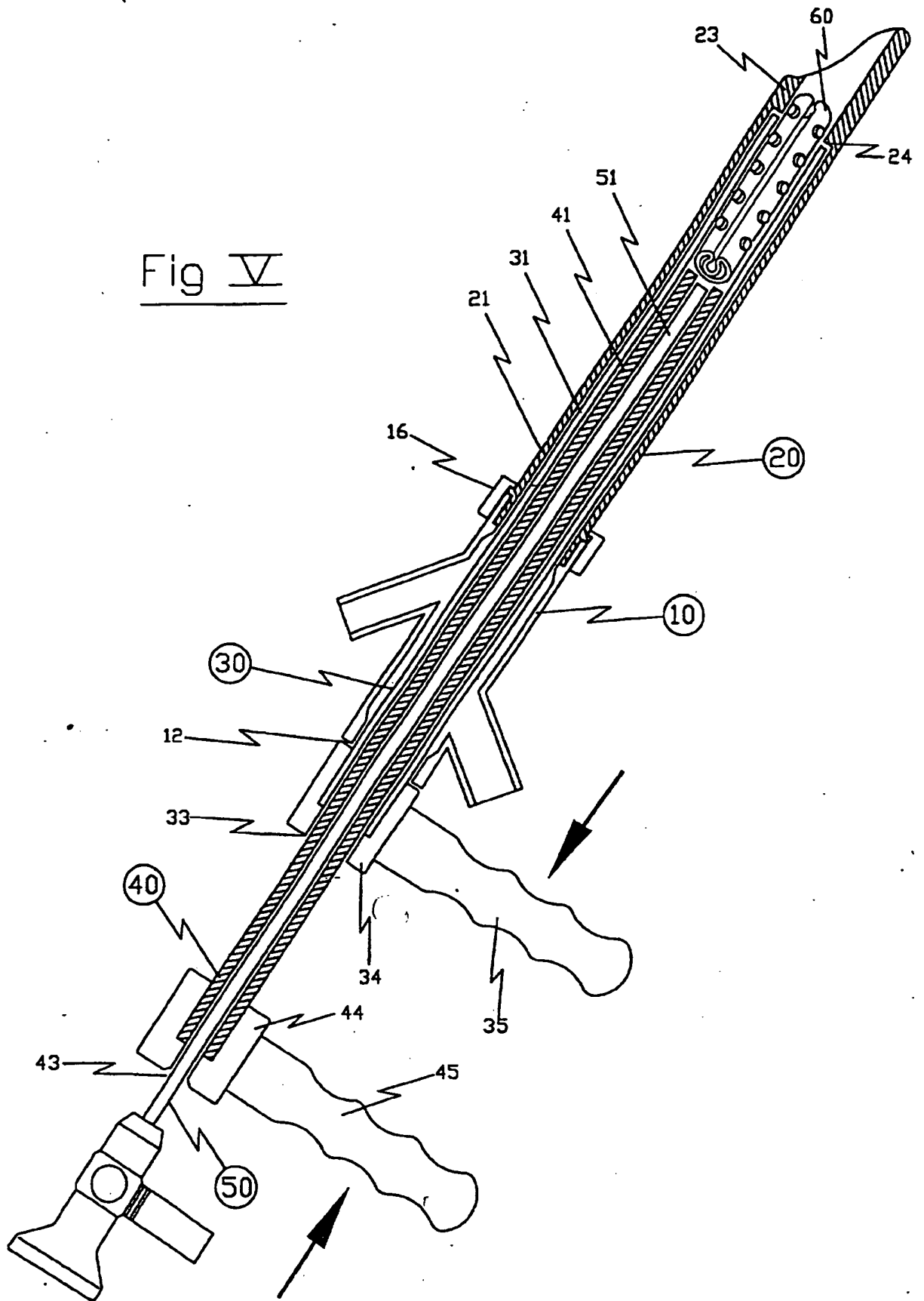


Fig VI

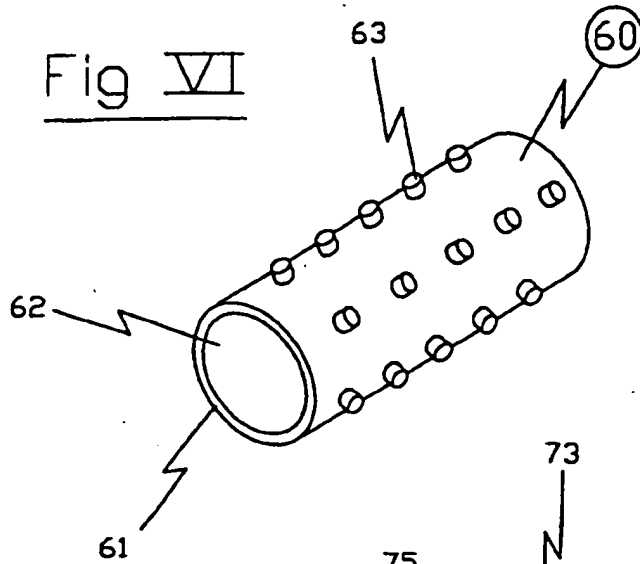


Fig VII

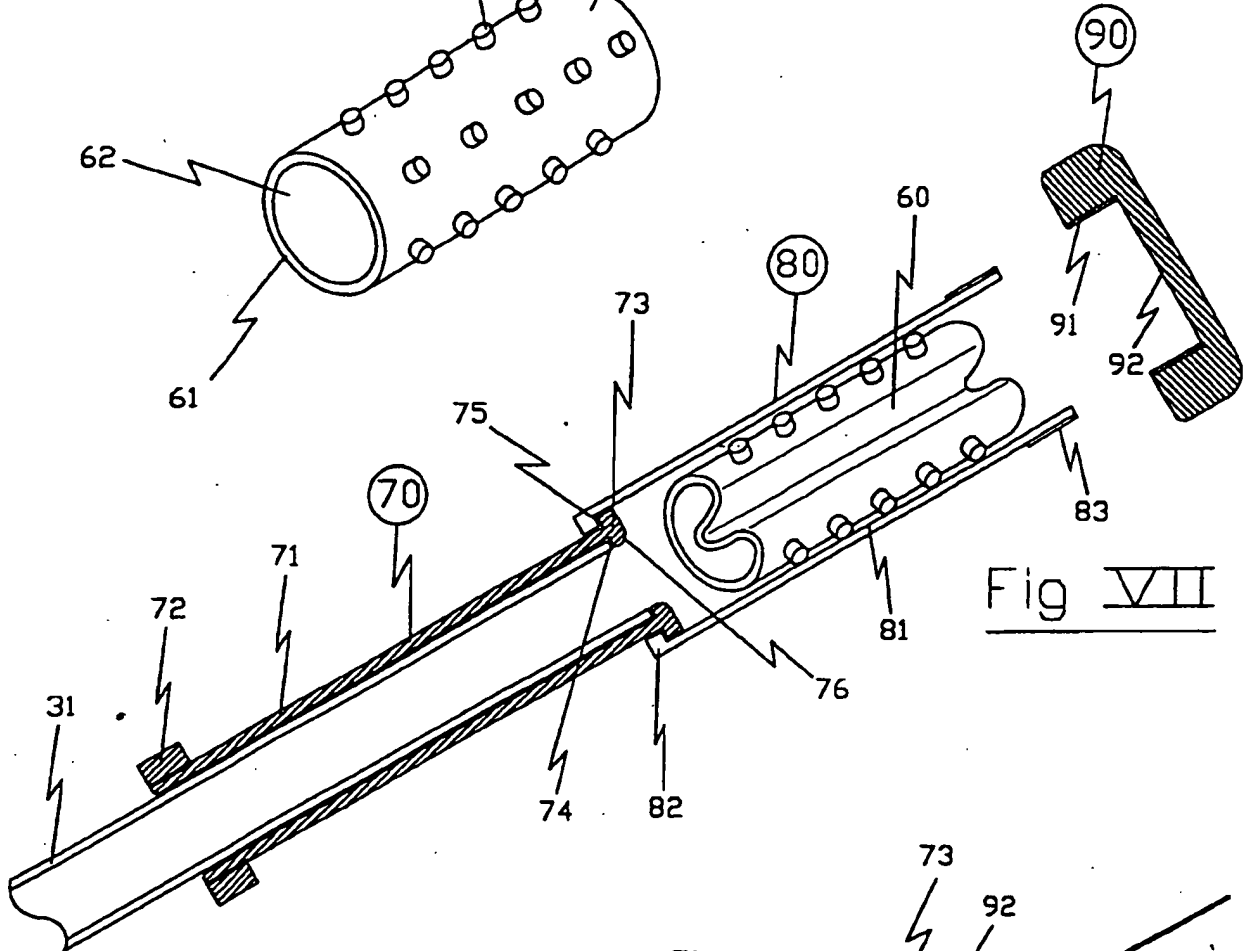
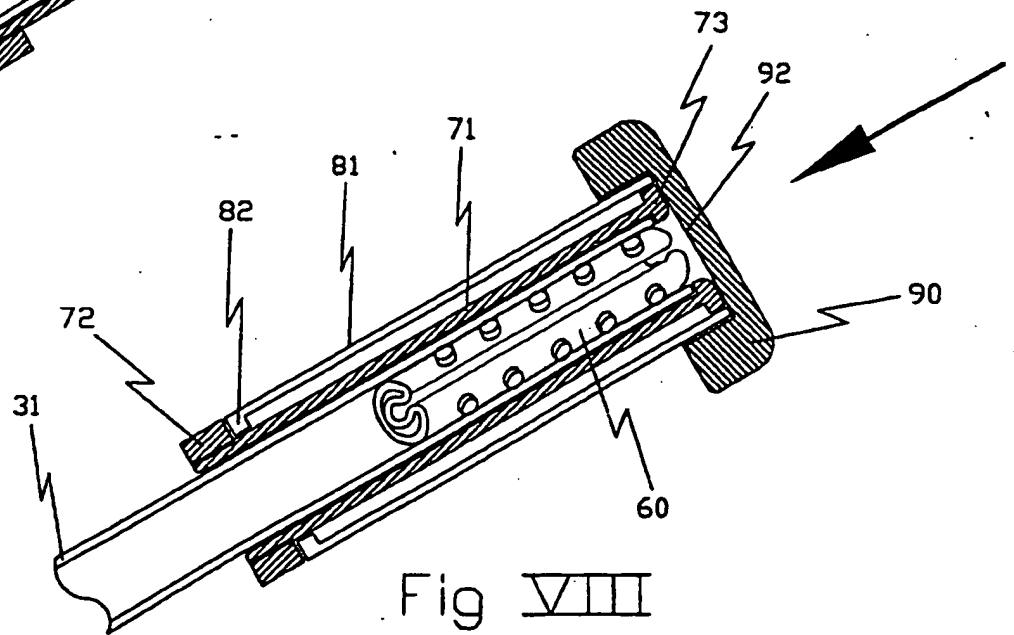


Fig VIII



CONTEXT OF THE INVENTION

5 The present invention relates to a system for setting a semi-rigid tubular endoprosthesis into the bronchus or the trachea of a patient whose clinical state justifies such a procedure. In particular, the positioning of such a tubular prosthesis makes it possible to clear a respiratory tract stricken with stenosis, or to support such a tract when it is failing.

Made out of a biocompatible material, such as silicon, the prostheses to which the present invention relates generally are in the form of a semi-rigid cylindrical tube whose external surface has a series of projecting cylindrical nipples distributed over said surface.
10 Said nipples are adapted to come into support against the inner wall of the respiratory tract involved, in order to anchor the endoprosthesis in said tract. These tubular prostheses, which are manufactured by the US corporation HOOD and the French corporation NOVATECH, originate from a concept described in the document WO 89 07916 (DUMON/1989).

15 The positioning of such a prosthesis in the bronchus or trachea of a patient is generally carried out under endoscopic control, and requires the use of a system for setting a semi-rigid tubular endoprosthesis usually having a bronchoscope and a device for introducing the prosthesis.

The generic term bronchoscope generally designates a rigid tubular instrument
20 designed to be introduced, through natural pathways, into the bronchus or the trachea of a patient, and allowing the operator to position an observation device (generally constituted of a rigid endoscope) and one or more surgical devices (such as, for example, forceps for extracting foreign bodies, biopsy forceps, suction catheter, laser resection fiber, prosthesis introducing device, ...). Such a bronchoscope has a tubular cannula whose
25 length and diameter correspond to the type of operation being performed, as well as to the anatomical characteristics of the patient, and a proximal base generally having an axial opening and two oblique lateral openings, said openings being adapted to the introduction of the observation device and of the surgical device(s), as well as to the implementation of a device for ventilating the patient. Depending on the manufacturers involved, these

bronchoscopes either are in the form of an integral instrument (such as the bronchoscope manufactured by the German corporation KARL STORZ, for example), or in the form of a modular instrument (such as the bronchoscope manufactured by the French corporation EFER, for example) constituted of a proximal base having a latching system which makes it possible to adapt, to said base, various types of cannulas each corresponding to a type of operation.

The document WO 89 07916 (DUMON/1989) describes a prosthesis introducing device constituted of a push tube slidably mounted around the cannula of a bronchoscope and allowing the operator to push the proximal end of a semi-rigid tubular prosthesis previously positioned so as to surround the distal end of said cannula. The interdependence of the bronchoscope and the prosthesis introducing device (the cannula of the bronchoscope serves a support tube for the prosthesis) inherent in such a concept, and the lodging of the prosthesis and prosthesis push tube around (and not within) the cannula of the bronchoscope cause the following drawbacks.

- The simultaneous introduction of the bronchoscope and of the prosthesis setting device preventing a pre-positioning of the bronchoscope into the patient's bronchus under endoscopic control.

- The use of a bronchoscope cannula having a large external diameter; said diameter being identical to the internal diameter of the tubular prosthesis.

- The displacement of a prosthesis having external asperities inside the patient's bronchus.

The prosthesis introducing device developed in 1989 by the French corporation EFER makes it possible to remedy the aforementioned drawbacks. In this system, the semi-rigid tubular prosthesis is bent longitudinally before being forcibly introduced within the distal end of a prosthesis holding tube having an external diameter that is slightly less than the internal diameter of the cannula of the bronchoscope used for the operation. The prosthesis holding tube is introduced into the axial opening constituting the proximal end of the base of a bronchoscope previously positioned under endoscopic control in the patient's bronchus or trachea. A prosthesis driver constituted of a cylindrical mandrel is then introduced into the proximal end of the prosthesis holding tube so as to allow the

operator to push the proximal end of the prosthesis which is thus going to position itself in the patient's bronchus or trachea. The drawbacks inherent in such a concept are as follows.

5 - Difficulty of introducing a previously bent tubular prosthesis into the distal end of a prosthesis holding tube having a small diameter.

 - Lack of mechanical safety causing the risk of using a long bronchus prosthesis holding tube in a short tracheal cannula, thereby inadvertently introducing the distal end of said prosthesis holding tube into the patient's trachea or bronchus.

 - Impossibility of introducing and setting the prosthesis under endoscopic control.

10 The present invention relates to the production of a system for setting an endotracheal or endobronchial semi-rigid tubular prosthesis resulting from the combination of a modular bronchoscope, a prosthesis introducing device, and an annex prosthesis compressing telescopic device. Said setting system makes it possible to overcome all of the aforementioned drawbacks.

SUMMARY DESCRIPTION OF THE INVENTION

The present invention relates to a system for setting an endotracheal or endobronchial semi-rigid tubular prosthesis, the system combining the devices that are described hereinafter.

5 **1. A modular bronchoscope including:**

1.1. A cylindrical tubular base whose distal end has a latching system adapted for connecting the interchangeable bronchial or tracheal cannulas described in 1.2.

1.2. Cylindrical tubular cannulas whose proximal end is compatible with the latching system of the base described in 1.1. The distal end of the axial channel of said cannulas
10 having an internal shoulder adapted to prevent the accidental introduction, into the patient's bronchus or trachea, of the distal end of the prosthesis holding tube described in 2.1.

2. **A prosthesis introducing device including:**

2.1. A prosthesis holder constituted of a cylindrical tubular base equipped with a lateral
15 handle, and of a cylindrical tube in the distal end of which a semi-rigid tubular prosthesis, previously bent longitudinally, can be forcibly introduced. The external diameter of the prosthesis holding tube is configured such that said tube can be introduced into the proximal end of the base of the bronchoscope described in 1.1, and can slide freely within the bronchial or tracheal cannula described in 1.2. The thickness of the prosthesis holding
20 tube is identical to the height of the internal shoulder provided in the distal end of the bronchial or tracheal cannula described in 1.2.

2.2. A prosthesis driver constituted of a cylindrical tubular base equipped with a lateral handle and of a cylindrical tube. The external diameter of the prosthesis driving tube is

configured such that said tube can be introduced into the proximal end of the base of the prosthesis holder described in 2.1, and can slide freely within the tube of said prosthesis holder. The thickness of the prosthesis driving tube is identical to the thickness of the tubular prosthesis previously introduced into the distal end of the prosthesis holding tube described in 2.1.

2.3. A rigid endoscope whose useful diameter is configured such that said endoscope can be introduced into the proximal end of the prosthesis driver described in 2.2, and can slide freely in the tube of said prosthesis driver.

3. A telescopic device for compressing a semi-rigid tubular prosthesis including:

3.1. A central cylindrical tube whose internal diameter is configured such that it makes it possible to manually introduce a tubular prosthesis, which is summarily bent in the longitudinal direction, into the distal end of said tube. The proximal end of said central tube has an internal shoulder adapted to serve as an abutment for the distal and proximal ends of the proximal cylindrical tube described in 3.2. The distal end of said central tube has an external threading making it possible to screw, onto said end, the sealing cap described in 3.3.

3.2. A proximal cylindrical tube whose internal diameter is configured such that the prosthesis holding tube described in 2.1, which is introduced beforehand into the proximal end of said proximal tube, can slide freely within said tube. The external diameter of said proximal cylindrical tube is configured such that said tube can slide freely in the internal shoulder constituting the proximal end of the central cylindrical tube described in 3.1. The proximal end of said proximal cylindrical tube has an external shoulder whose distal surface constitutes an "end" stop coming into contact with the proximal surface of the shoulder constituting the proximal end of the central cylindrical tube described in 3.1. The distal end of said proximal cylindrical tube has a flange having an internal shoulder and an external shoulder. The height of the external shoulder of said flange is calculated such

that the proximal cylindrical tube can slide freely within the central cylindrical tube described in 3.1, and that the proximal surface of said external shoulder constitutes a "beginning" stop coming into contact with the distal surface of the internal shoulder constituting the proximal end of said central cylindrical tube. The height of the internal shoulder of said flange is identical to the thickness of the prosthesis holding tube described in 2.1. The distal surface of the internal shoulder of said flange has a convex profile adapted to facilitate the forcible passage, into the distal end, of the prosthesis holding tube described in 2.1, and introduced beforehand into the proximal cylindrical tube, of the tubular prosthesis previously introduced into the central cylindrical tube described in 3.1.

3.3. A distal cap having an internal threading making it possible to screw said cap around the distal end of the central cylindrical tube described in 3.1.

SUMMARY PRESENTATION OF THE FIGURES ILLUSTRATING THE INVENTION

Figure I illustrates the structure of the modular bronchoscope implemented in the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention.

Figure IA shows a detailed axial cross-sectional view of the distal end of the cannula of the modular bronchoscope implemented in the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention.

Figure II illustrates the structure of the prosthesis holder constituting the first element of the prosthesis introducing device implemented in the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention.

Figure IIB shows a detailed axial cross-sectional view of the distal end of the prosthesis holding tube constituting the first element of the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention, the distal end in which a semi-rigid tubular endoprosthesis, bent in the longitudinal direction, is engaged.

Figure III illustrates the structure of the prosthesis driver constituting the second element of the prosthesis introducing device implemented in the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention.

Figure IIIB shows a detailed axial cross-sectional view of the distal end of the tube of the prosthesis driver constituting the second element of the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention.

Figure IV illustrates the structure of the endoscope constituting the third element of the prosthesis introducing device implemented in the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention.

5 Figure V illustrates the structure and implementation of the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention and results from the combination of the elements illustrated in the four preceding figures.

Figure VI illustrates the structure of an endotracheal or endobronchial semi-rigid tubular prosthesis of the type of those that are positioned by the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention.

10 Figures VII and VIII illustrate the structure and implementation of a telescopic device for compressing a semi-rigid tubular prosthesis constituting an accessory which advantageously completes the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

FIGURE I / FIGURE IA

Figure I and Figure IA illustrate the structure of the rigid bronchoscope used in the system for setting a semi-rigid tubular endoprosthesis which is the object of the present invention. Said bronchoscope is in the form of a modular instrument composed of a proximal base 10 and a series of interchangeable distal cannulas 20 capable of being associated with said base and adapted to be introduced, through natural pathways, into the trachea or bronchus of a patient.

The base 10 is constituted of a cylindrical tubular body whose distal end has a latching system 16 making it possible to surround, then to block the proximal end 26 of the interchangeable cannulas 20. The proximal end of the base 10 has an axial opening 12 whose diameter, which is identical to the internal diameter of said base, is greater than the internal diameters of the various cannulas that are capable of being associated with said base. The axial opening 12 allowing the introduction, into the bronchoscope of an endoscope, of various surgical devices and of the prosthesis introducing device described in the descriptions of Figures II, IIA, III, IIIA, IV, and V. The proximal base 10 further has an oblique lateral entry 18 allowing the connection of a patient ventilation system and an oblique lateral entry 17 adapted for the introduction of semi-rigid surgical devices.

The interchangeable cannulas 20 capable of being associated with the base 10 have a proximal end 26 that is compatible with the latching device 16 with which the distal end of said base is provided. The distal portion of a cannula 20 is constituted of a cylindrical tube 21 having an internal axial cylindrical channel 22, possibly having ventilation lateral openings 25, and whose geometrical characteristics are specific to the type of operation considered and to the patient's anatomy. The thickness of the distal end 23 of the cylindrical tube 21 of the cannulas used in the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention, is greater than the thickness of said tube 21, so as to narrow down the diameter of the distal end of the internal axial channel 22 of said cannulas, and to create an internal circular shoulder 24 preventing the accidental introduction, into the bronchus or trachea of a patient, of the distal end of the

cylindrical tube 31 of the prosthesis holder 30 described hereinafter in the description of Figure IIA; the distal end of said tube 31 being indeed dangerously aggressive due to the very thin tube.

FIGURE II / FIGURE IIA

5 Figure II and Figure IIA illustrate the structure of the prosthesis holder 30 which is a part of the prosthesis introducing device used in the system for setting a semi-rigid tubular endoprosthesis, which is the object of the present invention. Said prosthesis holder is constituted of a proximal base 34 and a cylindrical tube 31.

10 The base 34 is constituted of a cylindrical tubular body whose distal end is fixedly affixed to the proximal end of the tube 31. The proximal end of the base 34 has an axial opening 33 with a diameter that is identical to the internal diameter of the tube 31. The base 34 further has a lateral handle 35.

15 The cylindrical tube 31 constituting the distal portion of the prosthesis holder 30 has an external diameter that is slightly less than the internal diameter of the tube 21 of the cannula 20 of the bronchoscope described in the description of Figure I, such that the tube 31, which is introduced beforehand into the proximal axial opening 12 of the base 10 of said bronchoscope, can slide in the axial conduit 22 of said cannula. The internal diameter of the axial conduit 32 provided in the tube 31 is furthermore identical to the internal diameter of the distal end 23 of the cannula 20 of the bronchoscope. The arrangements
20 described above allow the distal end of the tube 31 to come into support against the internal shoulder 24 provided in the distal end of the cannula 20 of the bronchoscope into which said tube 31 has been introduced. The prosthesis holder 30 owes its name to the fact that the tubular prosthesis 60, which is described hereinafter in the description of Figure VI, is forcibly introduced into the distal end of the axial conduit 32 provided in the
25 tube 31, after being bent longitudinally.

FIGURE III / FIGURE IIIA

 Figure III and Figure IIIA illustrate the structure of the prosthesis driver 40 which is a part of the prosthesis introducing device used in the system for setting a semi-rigid

tubular endoprosthesis, which the object of the present invention. Said prosthesis driver is constituted of a proximal base 44 and a cylindrical tube 41. Said prosthesis driver has a cylindrical tubular structure having an axial cylindrical channel 42 having a proximal end 43 and a distal end 46.

5 The base 44 is constituted of a cylindrical tubular body whose distal end is fixedly affixed to the proximal end of the tube 41. The proximal end of the base 44 has an axial opening 43 with a diameter that is identical to the internal diameter of the tube 41. The base 44 further has a lateral handle 45.

10 The cylindrical tube 41 constituting the distal portion of the prosthesis driver 40 has an external diameter that is slightly less than the internal diameter of the tube 31 of the prosthesis holder 30 described in the description of Figure II, such that the tube 41, which is introduced beforehand into the proximal axial opening 33 of the base 34 of said prosthesis holder, can slide in the axial conduit 32 of said tube 31. The diameter of the axial conduit 42 provided in the tube 41 is furthermore configured such that the thickness
15 of said tube is identical, or substantially identical to the thickness of the cylindrical tube 61 constituting the structure of the semi-rigid tubular prosthesis described hereinafter in the description of Figure VI. The arrangements described hereinabove allow the distal end of the tube 41 to come into support on the proximal end of the prosthesis 60 housed in the distal end of the tube 31 of the prosthesis holder 30 into which said tube 41 has been
20 introduced.

FIGURE IV

Figure IV shows a rigid endoscope 50 having an endoscopic probe 51 associated with a base 54 having an observation cup 53 and a lateral connector 55 adapted for connecting a lighting cable.

25 The endoscopic probe 51 constituting the distal portion of the endoscope 50 has an external diameter that is slightly less than the internal diameter of the tube 41 of the prosthesis driver 40 described in the description of Figure III, such that the endoscopic probe 51, which is introduced beforehand into the proximal axial opening 43 of the base 44 of said prosthesis driver, can slide in the axial conduit 42 of said tube 41. The

arrangements described hereinabove allow the distal end of the endoscopic probe 51 of the endoscope 50 to come into contact with, or in the vicinity of the proximal end of the prosthesis 60 housed in the distal end of the tube 31 of the prosthesis holder 30, and thereby allow the operator to observe the ejection and the positioning of said prosthesis.

5 **FIGURE V**

Figure V illustrates the methods of implementing a system for setting a semi-rigid tubular endoprosthesis resulting from the association of a modular bronchoscope and a prosthesis introducing device. The bronchoscope described in the description of Figure I includes a base 10 and a cannula 20. The prosthesis introducing device includes a
10 prosthesis holder 30 described in the description of Figure II, a prosthesis driver 40 described in the description of Figure III, and an endoscope 50 described in the description of Figure IV.

The latching device 16 of the base 10 of the bronchoscope makes it possible to
15 fixedly associate the proximal end of the cannula 20 of the bronchoscope with the distal end of said base.

The distal end of the tube 31 of the prosthesis holder 30 is introduced into the proximal axial opening 12 of the base 10 of the bronchoscope. The prosthesis holder 30 is then pushed longitudinally slidably into the tube 21 of the cannula 20 of the bronchoscope until the distal end of the tube 31 of said prosthesis holder comes into
20 abutment on the circular shoulder 24 provided in the distal end 23 of the tube 21 of said cannula.

The distal end of the tube 41 of the prosthesis driver 40 is introduced into the proximal axial opening 33 of the base 34 of the prosthesis holder 30. The prosthesis driver 40 is then pushed longitudinally slidably into the tube 31 of the prosthesis holder 30 until
25 the distal end of the tube 41 of said prosthesis driver comes into abutment on the proximal end of the tubular prosthesis 60 bent longitudinally in the distal end of the tube 31 of said prosthesis holder.

The distal end of the endoscopic probe 51 of the endoscope 50 is introduced in the proximal axial opening 43 of the base 44 of the prosthesis driver 40. The endoscope 50

is then pushed longitudinally slidably into the tube 41 of the prosthesis driver 40 until the distal end of the endoscopic probe 51 of said endoscope comes into contact with, or in the vicinity of the proximal end of the tubular prosthesis bent longitudinally in the distal end of the tube 31 of the prosthesis holder 30.

5 Under these conditions, the operator can easily undertake the expulsion and setting of the tubular prosthesis 60 in the bronchus or trachea of a patient by simply closing his hand on the two lateral handles 35 and 45 affixed to the base 34 of the prosthesis holder 30 and to the base 44 of the prosthesis driver 40, respectively. The expulsion and the setting of the prosthesis are considerably facilitated by the arrangements inherent in the
10 present invention and disclosed hereinafter.

- Abutment of the distal end of the tube 31 of the prosthesis holder 30 on the cylindrical shoulder 24 provided in the distal end 21 of the cannula 20 of the bronchoscope, this arrangement preventing any accidental introduction of the distal end of said tube 31, which is dangerously sharp due to its cloth-like fineness, into the bronchus
15 or trachea of a patient.

- Equality of the internal diameter of the distal end 23 of the tube 21 of the cannula 20 of the bronchoscope and the internal diameter of the tube 31 of the prosthesis driver 30, this arrangement facilitating the expulsion of the semi-rigid tubular prosthesis 60.

- Equality of the thickness of the tube 41 of the prosthesis holder 40 and the
20 thickness of the tubular prosthesis 60, this arrangement also facilitating the expulsion of said endoprosthesis.

- Use of a prosthesis driver 40 having a tubular structure which allows the introduction of an endoscopic probe 51 into said prosthesis driver, and therefore the visual control of the expulsion and setting of the endoprosthesis 60 into the bronchus or trachea
25 of the patient.

FIGURE VI

Figure VI illustrates the structure of the semi-rigid tubular prostheses 60 implemented in the system for setting a tracheal or bronchial semi-rigid tubular endoprosthesis, which is the object of the present invention.

Made out of a biocompatible material, such as silicon, for example, these endoprostheses generally are in the form of a semi-rigid tube 61 having an internal cylindrical axial channel 62, and whose external surface has a series of projecting nipples, which are generally cylindrical and distributed over said surface.

5 **FIGURE VII**

Figure VII illustrates the structure of the telescopic device for compressing a semi-rigid tubular prosthesis which, associated with a prosthesis holder 30, allows an operator to longitudinally bend a semi-rigid tubular prosthesis 60 and to forcibly introduce it into the distal end of the small diameter cylindrical tube 31 of said prosthesis holder. Said
10 telescopic device has a proximal element 70 sliding in a central element 80 whose distal end is sealed by a distal element 90.

The central element 80 is constituted of a cylindrical tube 81 whose internal diameter is configured such that it allows the operator to easily introduce a semi-rigid tubular endoprosthesis 60, previously bent manually in the longitudinal direction, into the
15 distal end of said tube. The distal end of the tube 81 has an external threading 83, whereas its proximal end has an internal shoulder 82.

The proximal element 70 is constituted of a cylindrical tube 71 whose external diameter is slightly less than the internal diameter of the shoulder 82 with which the proximal end of the central element 80 is provided, and whose internal diameter is slightly
20 greater than the external diameter of the cylindrical tube 31 of the prosthesis holder 30 associated with the compression telescopic device. The distal end of the tube 71 has a flange 73 whose external diameter is slightly less than the internal diameter of the cylindrical tube 81 of the central element 80 of the compression telescopic device, and whose internal diameter is identical to the internal diameter of the cylindrical tube 31 of
25 the prosthesis holder 30 associated with the compression telescopic device. The proximal end of the tube 71 has an external threading making it possible to screw, on said end, a ring 72 whose external diameter is identical to the external diameter of the tube 81 of the central element 80 of the bending device.

The distal element 90 is a mere sealing cap having an internal threading 91 making it possible to screw said cap on the distal end of the central element 80 of the bending device.

5 The initial phase for implementing the telescopic device for compressing a semi-rigid tubular prosthesis, as illustrated by Figure VII, requires, under these conditions, to successively undertake the operations described hereinafter.

- Introduction of the proximal end of the proximal element 70 into the distal end of the central element 80.

- Translational displacement of the proximal element 70 in the central element 80, 10 such that the proximal surface 75 of the external shoulder of the flange 73 constituting the distal end of the proximal element 70 comes into abutment on the distal surface of the internal shoulder 82 constituting the proximal end of the central element 80.

- Screwing of the threaded ring 72 on the external threading machined around the proximal end of the proximal element 70.

- 15 - Introduction of the distal end of the cylindrical tube 31 of the prosthesis holder 30 into the proximal end of the proximal element 70.

- Translational displacement of the cylindrical tube 31 in the proximal element 70, such that the distal end of said tube comes into abutment on the distal surface 74 of the internal shoulder of the flange 73 constituting the distal end of said proximal element.

- 20 - Manual introduction of the tubular prosthesis 60, which is longitudinally summarily bent, into the distal end of the central element 80.

- Screwing of the distal cap 90 on the external threading machined around the distal end of the central element 80.

FIGURE VIII

25 Figure VIII illustrates the final phase for implementing the telescopic device for compressing a semi-rigid tubular prosthesis, which is the object of the present invention.

This final phase results from a manual thrust exerted by the operator on the distal surface of the distal sealing cap 90. This thrust causes the introduction of the tubular prosthesis 60 into the distal end of the tube 31 of the prosthesis holder 30. This

introduction results from a simultaneous occurrence of the kinematic displacements described hereinafter.

5 - Longitudinal translational displacement of the central element 80 about the proximal element 70 until the distal surface of the flange 73 constituting the distal end of the proximal element 70 comes into abutment on the bottom 92 of the distal cap 90, and the proximal surface of the shoulder 82 constituting the proximal end of the central element 80 simultaneously comes into abutment on the distal surface of the ring 72 constituting the proximal end of the proximal element 70.

10 - Forcible passage of the proximal end of the tubular prosthesis 60 into the progressive bottleneck constituted by the convex profile 76 provided on the distal surface of the internal shoulder of the flange 73 constituting the distal end of the proximal element 70, this forcible passage being followed by the progressive introduction of the tubular prosthesis 60 into the distal end of the tube 31 of the prosthesis holder 30.

SCOPE OF THE INVENTION

It is understood that the system for setting semi-rigid tubular endoprotheses, which is the object of the present invention, can relate to other anatomical conduits than the trachea or bronchus.

5 It is also understood that the present invention is in no way limited to the embodiments and applications that have just been explicitly described. On the contrary, the present invention encompasses all alternative embodiments that one with ordinary skills in the art can envision, without leaving the scope of the present invention, and more particularly the alternative embodiments mentioned hereinafter.

- 10 - Implementation of semi-rigid tubular endoprotheses having a different structure than that of the protheses described in the present invention.
- Use of a telescopic device for compressing semi-rigid tubular endoprotheses implementing more than two telescopic tubes.

CLAIMS

1. System for setting tracheal or bronchial semi-rigid tubular endoprotheses resulting from the combination and implementation of the following devices.

- A cylindrical tubular bronchoscope having a proximal base (10) and a distal cannula (20).

- A prosthesis introducing device including a cylindrical tubular prosthesis holder (30) configured such that the distal portion (31) of said prosthesis holder, which is previously introduced into the proximal axial opening (12) of the proximal base (10) of the bronchoscope, can slide in the distal cannula (20) of said bronchoscope. Said prosthesis introducing device further includes a cylindrical prosthesis driver configured such that the distal portion of said prosthesis driver, which is previously introduced into the proximal axial opening (33) of the prosthesis holder (30) suitably positioned in the bronchoscope, can slide in the distal portion (31) of said prosthesis holder. Said arrangements make it possible to cause the ejection of a prosthesis (60) previously bent longitudinally and forcibly introduced into the distal end of the distal portion (31) of the prosthesis holder (30).

Said system for setting semi-rigid tubular endoprotheses is characterized in that the prothesis driver (40) has a cylindrical tubular structure having an axial cylindrical channel (42) having a proximal end (43) and a distal end (46), said axial channel being configured so as to allow the introduction of the distal portion (51) of an endoscope (50) into the proximal opening (43) of said prosthesis driver. Said arrangements make it possible to perform an immediate endoscopic control of the ejection of the prosthesis caused by the pressure exerted by the distal end of the tube (41) of the prosthesis driver (40) on the proximal end of the semi-rigid tubular prosthesis (60), which is introduced beforehand into the distal end of the tube (31) of the prosthesis holder (30) suitably positioned in the cannula (20) of the bronchoscope, on the one hand, and of the setting of said prosthesis in the trachea or bronchus of the patient, on the other hand.

2. System for setting semi-rigid tubular endoprotheses according to claim 1, characterized in that the thickness of the cylindrical tube (41) constituting the distal portion of the prosthesis driver (40) is identical to the thickness of the cylindrical tube (61) of the semi-rigid tubular prosthesis (60) housed in the distal end of the tube (31) of the prosthesis holder (30). Said arrangements facilitate the ejection of said prosthesis.

3. System for setting semi-rigid tubular endoprotheses according to any of claims 1 or 2, characterized in that the proximal end of the prosthesis holder (30) is constituted of a cylindrical tubular base (34) having a lateral handle (35), and that the proximal end of the prosthesis driver (40) is constituted of a cylindrical tubular base (44) having a lateral handle (45). Said arrangements allow the operator to undertake the ejection of the prosthesis (60) by naturally closing his hand on the handles (35) and (45).

4. System for setting semi-rigid tubular endoprotheses according to any of the preceding claims, characterized in that the distal end (23) of the cannula (20) of the bronchoscope has an internal circular shoulder (24) offering a passage whose diameter is identical to the internal diameter of the tube (31) of the prosthesis holder (30) associated with said cannula, the shoulder thereby constituting a mechanical abutment for the distal end of said tube (31). Said arrangements prevent the accidental introduction of the distal end of said tube (31) into the bronchus or trachea of the patient.

5. System for setting semi-rigid tubular endoprotheses according to any of the preceding claims, characterized in that the ejection of the prosthesis (60) occurs through a passage channel having a constant diameter resulting from the fact that the internal diameter of the tube (31) of the prosthesis holder (30) is equal to the internal diameter of the distal end (23) of the cannula (20) of the bronchoscope. Said arrangements facilitate the ejection of the prosthesis (60).

6. System for setting semi-rigid tubular endoprotheses according to any of the preceding claims, characterized in that the introduction beforehand of the semi-rigid

tubular prosthesis (60) into the distal end of the tube (31) of the prosthesis holder (30) is facilitated by the implementation of a prosthesis compressing telescopic device whose structure results from the association of the elements described hereinafter.

5 - A proximal cylindrical tube (71) whose proximal end has an external threading and whose distal end has a flange (73) having an external shoulder and an internal shoulder. Said proximal tube (71) is configured so as to allow the tube (31) of the prosthesis holder (30), which is previously introduced into the proximal end of said proximal tube, to freely slide in said proximal tube until the distal end of said tube (31) comes into abutment on the proximal surface (74) of the internal shoulder of the flange (73).

10 - A central cylindrical tube (81) whose distal end has an external threading and whose proximal end has an internal shoulder (82). The internal diameter of the central tube (81) (configured so as to allow the sliding, in said tube, of the external shoulder of the distal flange (73) of the proximal tube (71)), and the internal diameter of the proximal internal shoulder (82) of the central tube (81) (configured so as to allow the sliding of the proximal tube (71) in said shoulder) are calculated so as to allow the proximal tube (71), which is previously introduced into the distal end of the central tube (81), to freely slide in said central tube until the proximal surface (75) of the external shoulder of the distal flange of the proximal tube (71) comes into contact with the distal surface of the proximal internal shoulder (82) of the central tube (81).

15 - A semi-rigid tubular prosthesis (60) introduced into the distal end of the central tube (81), after being summarily bent longitudinally.

20 - A sealing cap (90) which, screwed on the distal end of the central tube (81), makes it possible, by a mere longitudinal pressure, to slide the central tube (81) around the proximal tube (71), and whereby to introduce said prosthesis (60) into the distal end of the prosthesis holding tube (31) housed in the proximal tube (71). Said introduction is facilitated by the convex profile (76) of the distal surface of the internal shoulder of the distal flange of the proximal tube (71).

25 7. System for setting semi-rigid tubular endoprostheses according to claim 6, characterized in that a ring (72), screwed on the proximal end of the proximal tube

(71), makes it possible to avoid the accidental dismounting of the telescopic device resulting from the association of the proximal tube (71) and the central tube (81).

8. Apparatus for setting or ejection of a tracheal or bronchial semi-rigid tubular endoprosthesis comprising:

- a tubular bronchoscope having a proximal base and a distal cannula;
- a prosthesis introducing device including a tubular prosthesis holder, the prosthesis holder being insertable into the said bronchoscope via an opening in the said proximal base and slideable in the said distal cannula, and
- a prosthesis driver insertable into an opening in the proximal end of said prosthesis holder and slidable in the distal portion thereof so as to enable ejection of a prosthesis inserted in said distal portion,

wherein;

the prosthesis driver is of a tubular structure having an axial channel and a proximal opening adapted to receive a distal portion of an endoscope thereby permitting endoscopic control of the setting and/or ejection of a prosthesis inserted in the prosthesis holder when positioned in the distal cannular of the said bronchoscope.

9. Apparatus for the setting or ejection of a prosthesis substantially as described herein and with reference to the Figures I to VIII.

10. A method for the setting or ejection of a prosthesis substantially as described herein and with reference to the Figures I to VIII.



INVESTOR IN PEOPLE

Application No: GB 0003118.7

Examiner: Susan Chalmers
(Mrs)

Claims searched: 1-10

Date of search: 18 July 2000

Patents Act 1977 Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.R): A5R: RAT

Int CI (Ed.7): A61F: 2/06

Other: ONLINE: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
P,A	WO 99/25280 A (SCIMED LIFE SYSTEMS) see Figures	1,8
A	WO 89/07916 A (ARTEMIS) see Figures 6-10	1,8
A	US 5609627 (BOSTON SCIENTIFIC) see eg Figures 8A-8F	1,8

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.
& Member of the same patent family

A Document indicating technological background and/or state of the art
P Document published on or after the declared priority date but before the filing date of this invention.
E Patent document published on or after, but with priority date earlier than, the filing date of this application.